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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/338,221	06/22/1999	ELI PINES	11658/10	1129
26646	7590	02/17/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/338,221	Applicant(s) PINES ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 35-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 35-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-29-03 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 103*

3. Claims 1-14 and 35-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tripodi et al.

Note that the rejection has been changed since it no longer uses Miyano et al. as a secondary reference.

Applicants argue that the reference differs from the claimed invention in that Tripodi describes precipitation of fibrinogen with PEG-8000 twice, whereas the claimed invention uses PEG-1000 and precipitation is only performed once. Further, the percentage of fibrinogen recovered is 95% and not 90% as recited in the previous office action. The 90% reference makes reference to the recovery of the fibrinogen and not the percentage present in the therapeutic composition. Further, "Tripodi does not teach a therapeutic composition recovered from a process as recited in Claims 1, 2, 13, 36 and 37, wherein about 95%, or greater, of total protein present in said composition is fibrinogen, of which fibrinogen, at least about 56% is clottable fibrinogen." The

Art Unit: 1654

reference does not teach the percentage of clottable fibrinogen or range thereof present in the composition.

Applicant's arguments filed 10-29-03 have been fully considered but they are not persuasive.

The MPEP states “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777

F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113. Thus the mere fact that the reference discloses a different means of obtaining a product is inconsequential since the reference discloses the same product, i.e. a fibrinogen composition. As stated in the previous office action, the reference discloses the same product, at the same concentration, that is useful for the same purpose.


Applicants argue that the reference does not teach the percentage of fibrinogen in the composition claimed and does not teach the claimed percentage of “clottable fibrinogen.” However, the reference discloses states that “fraction procedure describes produces a composition containing at least about 90 to about 98 percent fibrinogen with a low level of conversion to fibrin.” (see page 8, lines 25-34). Note that after fractionation the product is lyophilized with a phosphate buffer system. Thus, in the final composition overall would contain between 90-98% of fibrinogen. As for the clottable fibrinogen, the reference discloses a fibrinogen composition similar to applicants claims. Therefore, the fibrinogen composition would necessarily have the least 56% as clottable fibrinogen.

The rejection is maintained.

Art Unit: 1654

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta  
Patent Examiner